

REMARKS

Claims 1 – 4, 8 and 17 - 20 are pending. No claims are hereby added or amended. Claim 8 is hereby cancelled.

All claims were rejected under 35 U.S.C. 103 as being obvious over Dutcher (US 4,381,013) in view of Evans, III, et al. (US 4,854,330). This rejection is again respectfully traversed.

In the Final Office Action, the examiner states as follows:

2. The rejection set forth in the previous office action (dated 10/28/10) states "Dutcher discloses a medical electrical lead (col. 3, lines 30-35) having a **J-shape stylet wire (depicted in figure 2; col. 3, lines 44-51)** to be slideably received within the lumen of the lead (depicted in the cutaway view of figure 7)". The only item depicted in figure 2, is the first inner portion of the improved stylet (see col. 2, lines 67-68). Therefore, the examiner clearly considers the stylet to be the first inner portion of the improved stylet. As such, the Applicant's argument that the rejection "is respectfully asserted to be deficient because it is not set forth with sufficient clarity" (see page 10 of the Remarks) is clearly false and without merit.

Based upon this text, the Attorney for Applicants now understands that the Examiner's rejection is expressly and clearly based upon the Examiner's assertion that the Inner stylet as illustrated in Figure 2 is the J-shaped stylet required by the claims. It is respectfully requested that the Examiner's further arguments remain consistent with this interpretation during the upcoming Appeal.

As noted previously, In order for the rejection to be proper under the recently issued Patent Office Guidelines for Section 103 rejections, the above argument would have to be factually correct and would have to conform to common sense and be set

forth with sufficient specificity to demonstrate that it does so. It is again respectfully asserted that the Examiner's argument fails.

In the Final rejection, the Examiner disputes the Applicants' assertion that the preformed curve in Dutcher is intended to hold the distal tip of the lead stationary while the screwdriver tip on the outer component of the lead is rotated. The Examiner's argument for rejection is expressly based upon this statement. One of skill in the art, familiar with screw-in leads of the type disclosed in Dutcher would appreciate that Applicants' assertion is clearly correct and the Examiner's above statement is incorrect.

Because the Examiner's argument is expressly based upon an incorrect statement, it fails to meet the standard of common sense and is per-se improper.

It is anticipated that the Examiner may argue that some sort of declaration would be necessary to support Applicants' assertion with regard to the operation of the Dutcher stylet and lead. However, Applicants respectfully assert that this aspect of Dutcher is in fact clear from the patent itself and in view of fundamental mechanical principles well understood by any person, regardless of skill in the art..

The distal end of the Dutcher lead of necessity needs to be stationary while the helix is screwed into tissue. Anyone, skilled or not, who has ever used a screwdriver understands this fact.

The outer portion of the Dutcher stylet which operates as the screwdriver thus of necessity must be held in the curved configuration against the heart wall by the preformed curve of the inner stylet. There is no other curved structure to hold it there. It does not require an advanced degree to understand that making the curved portion more flexible renders it less suited to holding the tip of the lead stationary while the outer stylet is rotated around it.

Expert testimony is not needed to explain basic mechanical principles.

Applicants respectfully repeat the following, none of which has been factually disputed by the Examiner.

In use, the majority of the Dutcher stylet is located in the lead body along its length as it extends through the vasculature (typically the subclavian or cephalic vein) and into the heart. The configuration of the lead body along this length is substantially constrained to the shape of the vasculature. In use, the distal end of the lead is located within the atrium, where the configuration of the lead body is unconstrained by the vasculature. It is for this reason that the distal end of the inner component of the Dutcher stylet is pre-formed into a curved configuration. As such, the distal, curved portion of the inner component is the portion of the stylet that has to most reliably hold its curved configuration in use. It correspondingly needs to be the least flexible portion of the stylet, not the most flexible. Tapering it would thus directly interfere with its functionality. This is the portion of the Dutcher lead that is least likely to benefit from being tapered. As such, the argument for obviousness defies common sense.

With allowance of claims 1 and 17, the withdrawn claims dependent thereon should also be allowed. Allowance of withdrawn claims 9 – 16 and 24 – 30 is therefore also respectfully requested.

Should any issues remain outstanding, the Examiner is urged to telephone the undersigned to expedite prosecution. The Commissioner is authorized to charge any deficiencies and credit any overpayments to Deposit Account No. 13-2546.

Respectfully submitted,

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Date

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